

Message

From: Orme-Zavaleta, Jennifer [Orme-Zavaleta.Jennifer@epa.gov]
Sent: 4/9/2021 12:59:48 PM
To: Thayer, Kris [thayer.kris@epa.gov]; Jones, Samantha [Jones.Samantha@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Bussard, David [Bussard.David@epa.gov]; Raffaele, Kathleen [raffaele.kathleen@epa.gov]
CC: Frey, Christopher [Frey.Christopher@epa.gov]
Subject: FW: Meeting with PRHE
Attachments: 13643_2018_Article_915.pdf; s13643-020-01490-8.pdf; IRIS Handbook_UCSF PRHE_ EPA IRIS_Final_0.pdf

See below fyi – of interest to IRIS and the RAF

Jennifer Orme-Zavaleta, PhD (she/her/hers)
Acting Assistant Administrator, and
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC 202-564-6620
Cell 919-699-1564

From: Frey, Christopher <Frey.Christopher@epa.gov>
Sent: Friday, April 9, 2021 8:18 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Rodan, Bruce <rodan.bruce@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>
Cc: Robbins, Chris <Robbins.Chris@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>
Subject: FW: Meeting with PRHE

Good Morning:

I am sharing an email I received from Tracey Woodruff's group as a follow-up to my meeting with them earlier this week. They have several key recommendations that they have shared, which I'd like to pass along for consideration.

I'll share the one regarding SAB with SABSO.

Best,

Chris

From: Chartres, Nicholas <Nicholas.Chartres@ucsf.edu>
Sent: Friday, April 9, 2021 7:54 AM
To: Frey, Christopher <Frey.Christopher@epa.gov>
Cc: Woodruff, Tracey <Tracey.Woodruff@ucsf.edu>
Subject: Meeting with PRHE

Dear Dr. Frey,

Thank you for taking the time to meet with us on Tuesday and for your efforts to work closely with your staff to strategically set new health-protective directions for the Office of Research and Development and the IRIS Program. We look forward to speaking with you in the future and we are happy to support your work in any way we can.

We wanted to provide some follow up to our discussion.

Systematic Review We believe the IRIS program is critically important to EPA's mission of protecting human health, and the recent release of the ORD Staff Handbook for Developing IRIS Assessments is an important milestone in the program's adoption of systematic review methods. We also think that the Handbook should serve as the basis for planning and conducting systematic reviews for hazard and risk assessment both for IRIS and across all of EPA's programs. That being said - we want to highlight that there are some methodological flaws in the Handbook systematic review process that need to be changed to be consistent with NAS recommendations. Our biggest concern is the IRIS risk of bias method that excludes studies based on one "critically deficient" domain, which could significantly reduce the available evidence to identify the harms caused by the toxic substances it evaluates. The NAS recommends methods proposed by NTP and our Navigation Guide approach. We have attached two relevant studies we have published on this issue and our public comments, and are happy to discuss further.

Non-cancer benefits tell fuller story of health impact Across EPA and in ORD calculating risk estimates for health effects other than cancer is one of our highest priorities and has also been identified by EJ communities as a high priority to appropriately identify toxic chemical exposures. Quantitative estimates would increase clarity regarding the risks being addressed under IRIS, enable improved benefit-cost analysis, and provide important information for decision-making. We have provided some of the background references on approaches and methods below and remain committed to helping EPA move this issue forward – such as presenting as part of the risk estimation process in IRIS assessments.

- The 2009 NAS report *Science and Decisions* presented several recommendations to EPA on adopting methods for calculating risk-specific doses for non-cancer health effects.^[1] The 2013 NAS report *Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic* also recommended derivation of risk-specific doses instead of an RfD.^[2] IRIS has previously committed, in a presentation to the NAS, to apply the International Programme on Chemical Safety (IPCS) probabilistic methodology in IRIS assessments for these purposes,^[3] and the 2018 NAS report *Progress Toward Transforming the Integrated Risk Information (IRIS) Program* considered this commitment to be responsive to earlier NAS recommendations concerning uncertainty analysis for IRIS toxicity values.^[4] Further, IRIS staff have published an application of the IPCS method for acrolein.^[5]

1. National Research Council. *Science and Decisions: Advancing Risk Assessment*. Washington, D.C.:National Academies Press; 2009. Ch 5
2. National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. Pp 90-91
3. National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. Pp 90-91
4. National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. Pp 119
5. Blessinger T, Davis A, Chiu WA, et al. Application of a unified probabilistic framework to the dose-response assessment of acrolein. *Environment international*. 2020;143:105953.

Conflict of Interest We commend EPA with the reset of the SAB and CASAC. We recommend the administration apply its own conflicts of interest policy (contained in its Peer-Review Handbook) across the administration. We also recommend the Agency make transparent any conflicts of interest of board members. It is critical that the Agency consider and manage financial conflicts of interest of incoming board members and balance committee

^[1] National Research Council. *Science and Decisions: Advancing Risk Assessment*. Washington, D.C.:National Academies Press; 2009. Ch 5

^[2] National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. Pp 90-91

^[3] National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. Pp 90-91

^[4] National Academies of Sciences, Engineering, and Medicine. 2018. *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*. Washington, DC: The National Academies Press. Pp 119

^[5] Blessinger T, Davis A, Chiu WA, et al. Application of a unified probabilistic framework to the dose-response assessment of acrolein. *Environment international*. 2020;143:105953.

members with members of NGOs. We have made recommendations on how COI should be managed on advisory boards and in research, which you can review [here](#).

Best Wishes,

Nick

Nicholas Chartres, PhD
Associate Director, Science & Policy
Program on Reproductive Health and the Environment (PRHE)
University of California, San Francisco
(415) 514-0517
Nicholas.chartres@ucsf.edu

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